

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE UNIVERSITY OF CHICAGO and)
BIO-RAD LABORATORIES, INC.)
Plaintiffs,)
v.) C.A. 15-152-RGA
10X GENOMICS, INC.)
Defendant.)

**MOTION FOR LEAVE TO PARTICIPATE
AS AMICUS CURIAE NOT IN SUPPORT OF ANY PARTY**

The Broad Institute, Inc. (“Broad”) hereby seeks leave to participate in this case as *amicus curiae* in the above-captioned litigation (“the subject litigation”) not in support of any party. Should the requested leave be granted, Broad further respectfully requests that the Court enter into the record as Broad’s *amicus curiae* Letter Memorandum, the proposed Letter Memorandum attached hereto as Exhibit 1 (the “Letter Memorandum”).

I. Legal Standard

This Court has allowed *amici* to file briefs presenting relevant factual background information. *United States v. Gordon*, 334 F. Supp. 2d 581, 582–86 (D. Del. 2004). Permitting *amici* to file briefs is advisable where they “can contribute to the court’s understanding” of the issues in a case—factual as well as legal. *Harris v. Pernsley*, 820 F.2d 592, 603 (3d Cir. 1987); *see Voices for Choices v. Illinois Bell Tel. Co.*, 339 F.3d 542, 545 (7th Cir. 2003) (*amicus* briefs are proper where they “will assist the judges by presenting ideas, arguments, theories, insights, facts, or data that are not to be found in the parties’ briefs”); *Community Ass’n for Restoration of Env’t v. DeRuyter Bros. Dairy*, 54 F. Supp. 2d 974, 975 (E.D. Wash. 1999) (“An *amicus* brief

should normally be allowed when . . . the *amicus* has unique information . . . that can help the court beyond the help that the lawyers for the parties are able to provide.”).

II. The Broad Has Unique Interests and Information—Beyond That of the Parties

A. Broad Can Contribute to the Court’s Understanding of the Issues

The identity of the non-party requesting to file a Letter Memorandum as *amicus curiae* is The Broad Institute, Inc. (“Broad”), also known as the Broad Institute of MIT and Harvard. Broad is a non-profit research organization with its principal laboratories and offices located in Cambridge, Massachusetts. Broad uses genomics to advance understanding of the biology and treatment of human disease, and to help lay the groundwork for next generation therapies.

Launched in May 2004, Broad is a not-for-profit research institute. It is a separate entity from the Massachusetts Institute of Technology and Harvard College, but affiliated with each of these institutions.

Broad is a mission-driven community that brings together researchers in medicine, biology, chemistry, computation, engineering, and mathematics from across MIT, Harvard, and Harvard-affiliated hospitals, along with collaborators around the world. Broad is committed to addressing medical challenges across the world, including by collaborating with scientists and public health experts to address important needs in developing countries. Broad works to build and sustain international consortia to speed discovery in areas including psychiatric research, infectious disease, cardiovascular disease, and cancer. Further, Broad is committed to making the extensive data, methods, and technologies it generates rapidly and readily accessible to the scientific community to drive biomedical progress around the world.

Broad makes tools, knowledge, methods and other IP (i) freely available to the academic and non-profit community and (ii) non-exclusively for others, except in unusual circumstances in which the public interest is better served by exclusive or semi-exclusive licensing. It is Broad’s

general position that all inventions made based in whole or in part on US Government funding should be similarly licensed whenever feasible to maximize public benefit.

I. Broad Extensively Uses the Single Cell Genomics Technology at Issue

Broad uses genomics to advance understanding of the biology and treatment of human disease, and to help lay the groundwork for next generation therapies. Broad participates in many US Government funded initiatives to leverage this work to advance understanding and treatment of human diseases.

Broad was instrumental in co-founding the independent Human Cell Atlas (“HCA”) Project that also uses such genomics. The HCA brings together an international community of biologists, clinicians, technologists, physicists, computational scientists, software engineers, and mathematicians. This community of scientists with diverse expertise share the common goal of creating a comprehensive reference map of all human cells as a basis for understanding human health and diagnosing, monitoring, and treating disease. Without such maps of different cell types, where they are located in the body, and the genes they express, science cannot describe all cellular activities and understand the biological networks that direct them. (See <https://www.broadinstitute.org/research-highlights-human-cell-atlas>, printout of webpage attached as Exhibit 2).

Broad currently extensively uses and needs to continue to freely and fully use that single cell genomics technology. Thus, Broad has a keen interest in the issues before the Court, including that Broad and the important research performed by Broad can, and will, be directly impacted the Court’s decisions on the remedies issues before the Court, especially the existence and scope of any permanent injunction and/or the level of ongoing royalties.

2. Interest of Broad and the Greater Public Interest

Broad has many interests that position it to offer unique and valuable perspectives on the remedies questions before the Court in the subject litigation, that will not likely be found in the parties' papers.

Broad can provide valuable assistance on the issues before the Court in the subject litigation. Broad, and Broad collaborators around the globe, are engaged in research advancing and using single-cell genomics to generate extensive data, methods, and technologies that are made rapidly and readily accessible to the scientific community to drive biomedical progress around the world.

B. Broad is Not Concerned With Which Parties Prevail; Rather How this Court's Orders Affect Research By Researchers at Broad and Leading Research Institutions

Broad uses 10X Genomics, Inc. ("10X") technologies and is a 10X customer. Broad also uses Bio-Rad Laboratories, Inc. ("Bio-Rad") technologies and is a Bio-Rad customer. Researchers of Broad are often the first to evaluate new equipment with presentation and publication of early access work important to evaluation of community in next purchasing decisions. In addition, members of Broad serve as consultants and advisors for both Bio-Rad and 10X. And members of Broad collaborate with members of the University of Chicago. Thus, Broad is not directly concerned with which parties prevail in this litigation; but rather is concerned with how this Court's Orders may affect the research done by members of Broad (and by extension other research institutions), including the ability to continue to generate data to be shared openly with the larger scientific community, for the greater benefit of humanity. And that concern extends not only to this matter brought against 10X but also with regard to other potential actions related to this technology including as brought by 10X or other commercial single cell instrument providers. While the parties rightfully have their own interests as their

prime objective—generally without regard to any effect on other parties or the customers of other parties—Broad is uniquely positioned to set forth the public interest which includes the ability to continue research no matter which commercial company may benefit. Thus Broad would maintain the same position if the parties were here reversed with 10X as the plaintiff patent owner, as for example in ITC Investigation number 337-TA-1100, which relates to 10X US Patent Nos. 9,644,204; 9,689,024; 9,695,468 and 9,856,530 arising from Section 337 Complaint filed by 10X alleging that Bio-Rad imports into the US, sells for importation and/or sells within the US after importation microfluidic systems, components thereof, and products containing the same that infringe one or more claims of these asserted patents of 10X’s patent portfolio which includes or should include patents developed in whole or in part with US Government funding.

C. Broad’s Many Single-Cell Genomics Techniques, Programs, Centers, and Participation in US Government and International Programs

Broad scientists develop and have developed single-cell genomics techniques and have many programs and centers that have at their core single-cell genomics techniques, e.g., programs and centers such as the Broad Epigenomics Program, the Broad Cell Circuits Program, the Broad Center for Cell Circuits, the Broad Genetic Perturbation Platform and Functional Genomics Consortium, the Broad Cancer Program, the Klarman Cell Observatory, and the Broad Program in Medical and Population Genetics (*see generally* entire Broad website at <https://www.broadinstitute.org>) and technologies such Drop Seq (*see, e.g.*, Macosko et al., “Highly Parallel Genome-wide Expression Profiling of Individual Cells Using Nanoliter Droplets,” *Cell*;161(5):1202-1214 (2015). doi: 10.1016/j.cell.2015.05.002, available at <https://www.ncbi.nlm.nih.gov/pubmed/26000488>, Perturb Seq (*see, e.g.*, Dixit et al., “Perturb-seq: Dissecting molecular circuits with scalable single cell RNA profiling of pooled genetic

screens,” Cell 167(7):1853–1866.e17 (2016), doi: 10.1016/j.cell.2016.11.038, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5181115/> and Adamson et al., “A multiplexed single-cell CRISPR screening platform enables systematic dissection of the unfolded protein response,” Cell 167(7): 1867–1882.e21 (2016), doi: 10.1016/j.cell.2016.11.048, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5315571/>, sNuc-Seq and DroNc-Seq (*see, e.g.*, Habib et al., “Div-Seq: Single-nucleus RNA-Seq reveals dynamics of rare adult newborn neurons,” Science 53(6302):925-8. (2016), doi: 10.1126/science.aad7038, available at <https://www.ncbi.nlm.nih.gov/pubmed/27471252> and Habib et al., “Massively parallel single-nucleus RNA-seq with DroNc-seq,” Nature Methods 14:955–958 (2017), available at <https://www.nature.com/articles/nmeth.4407>) and as participants in US government initiatives such as the Cancer Moonshot and International projects like the Human Cell Atlas.

These single-cell genomics techniques and programs and centers that have at their core single-cell genomics techniques have been developed and function through grants awarded to Broad scientists—including especially US Government grants (US public funds). In addition to the publications and public presentations mentioned herein, Broad has filed patent applications relating to inventions associated with these advances and practices the patent right to exclude as an ability to include by making the tools, knowledge, methods and other IP freely available to the academic and non-profit community and non-exclusively on reasonable terms for others.

D. Broad’s History of Creating Large Datasets and Unique Position in the Biomedical Research Ecosystem Makes Broad an Ideal Amicus Curiae

Dating back to the Human Genome Project in the 1990s, Broad scientists have been involved in systematic efforts to create large datasets intended to serve as a foundation for biological and medical studies in thousands of laboratories around the world. To maximize

impact, Broad seeks to make widely available to the entire scientific community through publicly available databases the data from such projects.

As an academic non-profit research institute, Broad recognizes the unique role that it and similar institutions play in propelling the biomedical ecosystem by exploring fundamental questions and working on risky, early-stage projects that often lack clear economic return. To maximize impact, Broad's work (including discoveries, data, tools, technologies, knowledge, and intellectual property) is made readily available by Broad, at no cost, to other academic and non-profit research institutions.

In Broad's view, industry plays an essential role in making commercial products available to speed research (such as reagents and technologies) and to directly benefit patients (such as diagnostics and therapeutics). Industry is often able to undertake efforts that cannot be readily undertaken in academia — because, for example, they require funding at a scale that can typically be obtained only from private investment; specialized scientific expertise about drug development that may not be readily available in academia; or the ability and infrastructure to run large clinical trials.

Clearly, academic non-profit research institutions and industry are at different positions in the biomedical ecosystem. However, for the biomedical ecosystem to function properly, academic non-profit research institutions and industry should not be at loggerheads, but should function symbiotically.

Thus, while industry is an important part of the biomedical ecosystem, industry should not be a bottleneck through patent-based permanent injunctions or onerous royalty rates to the detriment of research and the academic and non-profit research institutions, such as Broad, that explore fundamental questions and work on risky, early-stage projects that often lack clear

immediate or direct economic return—especially if the industry-controlled patents being enforced were generated through US Government funding, as in this case.

Therefore, to encourage the academic non-profit research institutions and industry to function symbiotically, Broad ensures that its work ultimately benefits patients, by interacting with industry through (i) engaging in scientific collaborations with industrial partners who share Broad’s vision around a scientific area, and (ii) responsible licensing of innovations to industry.

With respect to commercial licensing, Broad’s most important consideration is maximizing public benefit. In most cases, Broad believes that the goal of maximizing public benefit is best accomplished through non-exclusive licensing, which allows many companies to use innovations and thus compete to bring to market products incorporating them—especially with respect to technologies developed from US Government grants (US public funds).

To ensure that scientific innovation benefits human health, scientists must also try to ensure that cutting-edge technologies are used in a socially responsible way. Broad often places policy restrictions on use of Broad-developed technologies, data and techniques, to prohibit uses that would be socially irresponsible based on current scientific knowledge and societal consensus. Broad’s history and unique position in the biomedical research ecosystem makes Broad an ideal *amicus curiae*.

E. Broad Also Presents to the Court the Greater Public Interest

There is also the greater public interest that Broad readily presents to the Court. The single-cell genomics technology at issue in the subject litigation is in use by Broad and its collaborators, including the US National Institutes of Health (NIH), in NIH-initiated and funded projects.

Broad, along with the NIH, the Dana-Farber Cancer Institute, Harvard University, the National Cancer Institute and the US Food and Drug Administration and other academic and

commercial collaborators, is a member of the NIH project called FNIH (Foundation for the National Institutes of Health) Biomarkers Consortium - Chemotherapeutic Impact on the Immune MicroEnvironment (see <https://fnih.org/what-we-do/biomarkers-consortium/programs/chiime>). This public interest NIH project seeks a better understanding of the tumor immune microenvironment (TME). By analysis of samples both before and after chemotherapy, the multi-institution team is using the single-cell genomics technology at issue in the subject litigation, to identify ways to predict and explain clinical therapy responses, positive and negative. This will allow patients to be properly matched to existing therapies. This work also finds new vulnerabilities that may be suitable for therapeutic intervention, especially human cancer treatments that harness the body's immune system.

In addition, Broad is part of the NCI Human Tumor Atlas Network, a part of the Cancer MoonshotSM, which is a US government project that uses such genomics. This is a major NIH project that involves fresh tumor samples from human patients that must be processed immediately and in a cost-effective manner. These initiatives require much data to be collected from many human samples. Use of the single-cell genomics at issue in the subject litigation, by Broad, NIH and others was envisioned by the Program seeking to improve the ability to understand and treat disease. (See, e.g., <https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/implementation/human-tumor-atlas> and <https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative>).

These Broad-NIH projects illustrate that there is a significant public interest as to use of the single-cell genomics at issue in the subject litigation, and that in its proposed Letter Memorandum, Broad is speaking not only on behalf of itself, but also on behalf of the greater public interest with respect to the effects of an injunction here and generally for this type of

technology. In short, the public, via Broad, NIH and collaborators of the NIH and Broad, needs unfettered access to high throughput, robust single-cell genomics technology at issue in the subject litigation.

F. Broad Presents to the Court Interests that Diverge From Those of the Parties

In view of these interests that diverge significantly from the commercial interests of the primary parties to the subject litigation, in its proposed Letter Memorandum, Broad presents ideas, arguments, theories, insights, facts, and data that are unique, not likely to be found in the parties' papers, that will contribute to the Court's understanding of the issues in the subject litigation (both factual and legal), and that will greatly assist the Court in deciding the issues before it in the subject litigation.

III. Conclusion

It is respectfully submitted that Broad has demonstrated it is a proper entity to be an *amicus curiae*, that Broad's Letter Memorandum as *amicus curiae* will assist the Court, and thus that it is appropriate to grant Broad's request to participate as *amicus curiae* in the subject litigation.

WHEREFORE, Movant, The Broad Institute, Inc. respectfully requests that this Court grant this motion for leave to participate as *amicus curiae*, and enter into the record as Broad's *amicus curiae* the Letter Memorandum attached hereto as Exhibit 1.

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